REMARKS/ARGUMENT

Claims 20-29 and 31-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Infeld et al. WO02/089835 (Infield) in view of Babcock et al. EP1027886 (Babcock). This rejection is respectfully traversed for the following reasons.

Infeld discloses a solid unit oral pharmaceutical dosage form of amorphous nelfinavir mesylate and a poloxamer. Abstract. The solid dosage form is produced by a hot melt granulation process comprising blending the nelfinavir mesylate and the copolymer, and heating the blend to a temperature less than the decomposition temperature of the drug. This process results in granules of the drug embedded in the poloxamer. Page 6, lines 8-14. Other excipients can be included in the melt granulation. Page 6, lines 20-21. The Examiner concedes that Infeld does not disclose the inclusion of a stabilizing polymer such as HPMCAS in the granules. Indeed, Infeld does not disclose or suggest that the nelfinavir compositions require any stabilization, let alone by a stabilizing polymer. This fact alone rebuts the proposition that one of ordinary skill would be motivated to look to Babcock for a stabilizing polymer.

The Examiner argues that Babcock shows a solid dispersion of a low-solubility drug and a polymer, contending that the preferred polymer is cellulosic, citing Babcock page 29, lines 19-36, or Babcock claims 1-6. The Examiner appears to have concluded that a cellulosic polymer is preferred because Babcock claim 6 reads, "The composition of claim 1 wherein said polymer is cellulosic." From this, the Examiner seems to reason that, since HPMCAS is a cellulosic polymer, Babcock discloses HPMCAS as a preferred stabilizing polymer for the dispersion. However, the Examiner appears to have overlooked the limitation in Babcock claim 1 that the polymer has "a glass transition temperature of at least 100°C measured at 50% relative humidity." The Babcock specification makes it clear that HPMCAS is not included within the scope of the invention when used alone because it does not satisfy this glass-transition temperature requirement. Babcock at paragraphs [0057]-[0058]. Note that independent claim 20 recites in subparagraph (c) inclusion of a stabilizing polymer "selected from the group consisting of" HPMCAS and CMEC. The transitional phrase "consisting of" excludes

any ingredient not specified in the claim. *In re Gray*, 11 USPQ 255 (CCPA 1931). In other words, claim 20 is limited to inclusion of a polymer that is either HPMCAS alone or CMEC alone. But Babcock clearly teaches that HPMCAS alone is unsuitable for stabilizing his composition. Given this, there is submitted to be another reason there is no motivation to include HPMCAS in the Infeld composition. (And Babcock does not even disclose CMEC as a stabilizing polymer.)

The Examiner further asserts that "HPMC will stabilize amorphous low-soluble drugs so that they do not undergo change to crystalline form overtime [*sic*] during storage," citing Babcock at page 3, lines 5-14. But Babcock makes no reference to HPMC or HPMCAS at the place cited.

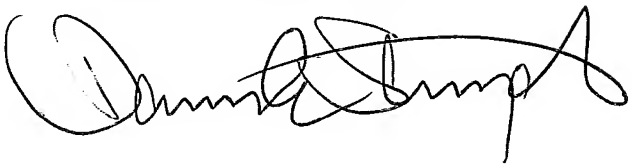
The Examiner also contends that a preferred exemplary dispersion of Babcock contains 30% HPMCAS, pointing to page 18, lines 20-25, or Ex. No. 5 in Table 1. However, this dispersion in Babcock contains 33.3 wt% drug, 33.3 wt% of the polymer CAP, and 33.3 wt% HPMCAS. CAP is present because of its high glass-transition temperature at high relative humidity. Babcock at [0058]. Perhaps more importantly, the fact that CAP was included with HPMCAS undercuts the Examiner's implicit contention that HPMCAS alone is suggested by the prior art to be suitable as a stabilizing polymer.

For the foregoing reasons, one of ordinary skill in the art would not find it obvious to add HPMCAS as taught by Babcock to the compositions of Infeld.

Claims 20-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Beyerinck et al. US 2003/0163931 (Beyerinck). The Examiner acknowledges at page 2 of the Final Rejection that the priority date for the instant application is December 31, 2003. Since Beyerinck published on September 4, 2003, it is only available under 35 USC 102(e). Beyerinck and the instant invention were subject to assignment to Pfizer, Inc. at the time the instant invention was made. Accordingly, pursuant to 35 USC 103(c), Beyerinck is not available as prior art under 103(a), so withdrawal of this rejection is requested.

Early and favorable reconsideration is respectfully solicited.

Respectfully submitted,



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